1 Identification of the substance/mixture and of the company/undertaking

· Product identifier

· Trade name: Ultradent™ EDTA 18% Solution
· Article number: 66009
· Index number: SDS 32-001.08
· Relevant identified uses of the substance or mixture and uses advised against
  Professional Dental Root Canal Cleansing & Conditioning Agent
· Application of the substance / the mixture
  Professional Dental Root Canal Cleansing & Conditioning Agent

· Details of the supplier of the safety data sheet
· Manufacturer/Supplier:
  Ultradent Products Inc.
  505 W. Ultradent Drive (10200 S)
  South Jordan, UT 84095-3942
  USA
  onlineordersupport@ultradent.com

  EC Responsible Person
  Ultradent Products GmbH
  Am Westhover Berg 30
  51149 Cologne Germany
  Email: infoDE@ultradent.com
  Emergency Phone: +49(0)2203-35-92-0

· Further information obtainable from: Customer Service
· Emergency telephone number:
  CHEMTREC (NORTH AMERICA) :(800) 424-9300
  (INTERNATIONAL) : +(703) 527-3887

2 Hazards identification

· Classification of the substance or mixture
  · Classification according to Regulation (EC) No 1272/2008
    GHS07
    Skin Irrit. 2 H315 Causes skin irritation.
    Eye Irrit. 2 H319 Causes serious eye irritation.

· Label elements
  · Labelling according to Regulation (EC) No 1272/2008
    The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.
  · Hazard pictograms GHS07
  · Signal word Warning
  · Hazard statements
    H315 Causes skin irritation.
    H319 Causes serious eye irritation.
  · Precautionary statements
    P101 If medical advice is needed, have product container or label at hand.
Trade name: Ultradent™ EDTA 18% Solution

P102 Keep out of reach of children.
P103 Read label before use.
P264 Wash thoroughly after handling.
P280 Wear protective gloves / eye protection / face protection.
P302+P352 IF ON SKIN: Wash with plenty of water.
P321 Specific treatment (see on this label).
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313 If skin irritation occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.
P337+P313 If eye irritation persists: Get medical advice/attention.

Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.
vPvB: Not applicable.

3 Composition/information on ingredients

- Chemical characterisation: Mixtures
- Description: Mixture of substances listed below with nonhazardous additions.
- Dangerous components:

<table>
<thead>
<tr>
<th>CAS: 10378-23-1</th>
<th>EDTA Tetrasodium Salt</th>
<th>&gt;10-≤25%</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC number: 600-485-4</td>
<td>Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335</td>
<td></td>
</tr>
</tbody>
</table>

Additional information: For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

- Description of first aid measures
- General information: Immediately remove any clothing soiled by the product.
- After inhalation:
  Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.
- After skin contact:
  Immediately wash with water and soap and rinse thoroughly.
  If skin irritation continues, consult a doctor.
- After eye contact:
  Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- After swallowing:
  If symptoms persist consult doctor.
- Information for doctor:
  - Most important symptoms and effects, both acute and delayed No further relevant information available.
  - Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Firefighting measures

- Extinguishing media
- Suitable extinguishing agents:
  Foam, dry chemical, carbon dioxide
  Use fire extinguishing methods suitable to surrounding conditions.
- Special hazards arising from the substance or mixture No further relevant information available.
6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**: Wear protective clothing. 
- **Environmental precautions**: Do not allow to enter sewers/surface or ground water. 
- **Methods and material for containment and cleaning up**: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). 
- **Reference to other sections**: See Section 7 for information on safe handling. 
  See Section 8 for information on personal protection equipment. 
  See Section 13 for disposal information.

7 Handling and storage

- **Handling**: 
- **Precautions for safe handling**: Avoid release to the environment 
- **Information about fire and explosion protection**: No special measures required. 
- **Conditions for safe storage, including any incompatibilities** 
- **Storage**: 
  - **Requirements to be met by storerooms and receptacles**: No special requirements. 
  - **Information about storage in one common storage facility**: Store away from oxidising agents. 
- **Further information about storage conditions**: See product labelling. 
  - **Specific end use(s)**: Professional Dental Root Canal Cleansing & Conditioning Agent

8 Exposure controls/personal protection

- **Additional information about design of technical facilities**: No further data; see item 7. 
- **Control parameters** 
  - **Ingredients with limit values that require monitoring at the workplace**: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace. 
- **Additional information**: The lists valid during the making were used as basis.
- **Exposure controls** 
- **Personal protective equipment**: Keep away from foodstuffs, beverages and feed. 
  - **General protective and hygienic measures**: 
    - Immediately remove all soiled and contaminated clothing. 
    - Wash hands before breaks and at the end of work. 
    - Avoid contact with the eyes and skin. 
- **Respiratory protection**: Not required.
Protection of hands:

- **Protective gloves**
  
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

Material of gloves

The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection:

- **Tightly sealed goggles**

Body protection: Protective work clothing

---

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
  
  - **General Information**
    
    Appearance:
    
    - **Form:** Liquid
    - **Colour:** Colourless
    - **Odour:** Odourless
    - **Odour threshold:** Not determined.
  
  - **pH-value at 20 °C:** 10.9-11.1
  
  - **Change in condition**
    
    - **Melting point/freezing point:** Undetermined.
    - **Initial boiling point and boiling range:** Undetermined.
  
  - **Flash point:** Not applicable.
  
  - **Flammability (solid, gas):** Not applicable.
  
  - **Decomposition temperature:** Not determined.
  
  - **Auto-ignition temperature:** Product is not selfigniting.
  
  - **Explosion properties:** Product does not present an explosion hazard.
  
  - **Explosion limits:**
    
    - **Lower:** Not determined.
    - **Upper:** Not determined.
  
  - **Vapour pressure:** Not determined.
  
  - **Density at 20 °C:** 1.11 g/cm³

(Contd. on page 5)
10 Stability and reactivity

- Reactivity: Stable
- Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- Possibility of hazardous reactions: No dangerous reactions known.
- Conditions to avoid: No further relevant information available.
- Incompatible materials:
  - Oxidizing agents
  - Alkalis
  - Acids
- Hazardous decomposition products:
  - Sodium Hydroxide
  - Nitrogen oxides
  - Carbon monoxide and carbon dioxide
  - Ammonia

11 Toxicological information

- Information on toxicological effects
- Acute toxicity: Based on available data, the classification criteria are not met.
- Primary irritant effect:
- Skin corrosion/irritation
  - Causes skin irritation.
- Serious eye damage/irritation
  - Causes serious eye irritation.
- Respiratory or skin sensitisation
- CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)
- Germ cell mutagenicity
- Carcinogenicity
- Reproductive toxicity
- STOT-single exposure
- STOT-repeated exposure Based on available data, the classification criteria are not met.

(Contd. on page 6)
12 Ecological information

- **Toxicity**
  - **Aquatic toxicity**: No further relevant information available.
  - **Persistence and degradability**: No further relevant information available.

- **Behaviour in environmental systems:**
  - **Bioaccumulative potential**: No further relevant information available.
  - **Mobility in soil**: No further relevant information available.

- **Additional ecological information:**
  - **General notes:**
    Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
    Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
    Rinse off of bigger amounts into drains or the aquatic environment may lead to increased pH-values. A high pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably reduced, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

- **Results of PBT and vPvB assessment**
  - **PBT**: Not applicable.
  - **vPvB**: Not applicable.

- **Other adverse effects**: No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
  - **Recommendation**: Do not allow product to reach sewage system.

- **Uncleaned packaging**:
  - **Recommendation**: Disposal must be made according to official regulations.

14 Transport information

- **UN-Number**
  - **ADR, ADN, IMDG, IATA**: Not regulated

- **UN proper shipping name**
  - **ADR, ADN, IMDG, IATA**: Not regulated

- **Transport hazard class(es)**
  - **ADR, ADN, IMDG, IATA**: Not regulated

- **Packing group**
  - **ADR, IMDG, IATA**: Not regulated

- **Environmental hazards**: Not applicable.

- **Special precautions for user**: Not applicable.

- **Transport in bulk according to Annex II of Marpol and the IBC Code**: Not applicable.
Trade name: Ultradent® EDTA 18% Solution

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- Chemical safety assessment:
  Device is biocompatible when used as directed by dental professionals per ISO 10993-1

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- Relevant phrases
  H315 Causes skin irritation.
  H319 Causes serious eye irritation.
  H335 May cause respiratory irritation.

- Department issuing SDS: Regulatory Affairs
- Contact: Customer Service
- Abbreviations and acronyms:
  ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
  IMDG: International Maritime Code for Dangerous Goods
  IATA: International Air Transport Association
  GHS: Globally Harmonised System of Classification and Labelling of Chemicals
  EINECS: European Inventory of Existing Commercial Chemical Substances
  ELINCS: European List of Notified Chemical Substances
  CAS: Chemical Abstracts Service (division of the American Chemical Society)
  VOC: Volatile Organic Compounds (USA, EU)
  PBT: Persistent, Bioaccumulative and Toxic
  vPvB: very Persistent and very Bioaccumulative
  Skin Irrit. 2: Skin corrosion/irritation – Category 2
  Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
  STOT SE 3: Specific target organ toxicity (single exposure) – Category 3